David Garrett

STATE OF MISSOURI
DEPARTMENT OF NATURAL RESOURCES

Jeremiah W. (Jay) Nixon, Governor • Mark N. Templeton, Director

www.dnr.mo.gov

RCAP RECEIVED
MAR 15 2010

March 12, 2010

CERTIFIED MAIL – 7004 1160 0000 8177 3285
RETURN RECEIPT REQUESTED

File

Mr. Tom Meitner
Environmental Division
Modine Manufacturing Company
1500 DeKoven Avenue
Racine, WI 53403-2552

RE: Final Resource Conservation and Recovery Act Facility Investigation Report
Modine Manufacturing Company, Camdenton, Missouri
EPA ID# MOD062439351

Dear Mr. Meitner:

This letter is to notify you that the Missouri Department of Natural Resources and the U.S. Environmental Protection Agency Region VII reviewed Modine Manufacturing Company's Final Resource Conservation and Recovery Act (RCRA) Facility Investigation (RFI) Report, dated July 2009. Modine Manufacturing Company submitted the RFI Report as required by Modine Manufacturing Company's Corrective Action Abatement Order on Consent, Number 99-HW-002, dated July 20, 1999. We have the following comments and requests for additional information for your review and response. The U.S. Environmental Protection Agency's comments regarding the Human Health Risk Assessment portion of the RFI Report are also enclosed with this letter. Please address the individual comments by submitting a revised RFI Report to the Missouri Department of Natural Resources, and two copies to the U.S. Environmental Protection Agency, within 45 days of receiving this letter.

If you have any questions regarding this letter or would like to schedule a conference call to discuss the enclosed comments, please contact me at the Missouri Department of Natural Resources, 7545 South Lindbergh, Suite 210, St. Louis, MO 631250, by telephone at (314) 416-2960 or 1-800-361-4827, or by e-mail at christine.kump@dnr.mo.gov. If you have

504237
RCRA

specific questions regarding the Human Health Risk Assessment comments please contact Mr. David Garrett, with the U.S. Environmental Protection Agency, at (913) 551-7159, or by e-mail at David.Garrett@epamail.epa.gov. Thank you.

Sincerely,

HAZARDOUS WASTE PROGRAM

for CKM

Christine Kump-Mitchell, P.E.
Environmental Engineer
Permits Section

CKM:sw

Enclosures

c: Mr. David Garrett, Project Manager, U.S. EPA Region VII ✓
Mr. Jeremy Johnson, U.S. EPA Region VII
Ms. Monica Martin, Project Manager, CH2MHill
Southwest Regional Office, Missouri Department of Natural Resources

SPECIFIC COMMENT

1. **Section 2.6, Land Use, Page 2-3:** This section states that this property has been used for industrial purposes since 1967 and will continue to be zoned as industrial use for the foreseeable future. However, as discussed in the Missouri Department of Natural Resources' June 26, 2008, comment letter, the Resource Conservation and Recovery Act Facility Investigation Report was completed prior to Modine Manufacturing Company's corporate headquarters announcing the closure of the Camdenton, Missouri, plant. Modine should address how the closure of the Camdenton Plant will affect future land use of the site. The July 2009 final Resource Conservation and Recovery Act Facility Investigation Report does not address this comment. The report should also discuss any current deed restrictions or zoning ordinances designating the site as industrial as well as the draft environmental covenant that will be placed on the property.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 7
901 NORTH 5TH STREET
KANSAS CITY, KANSAS 66101

DEC 1 1 2009

Mr. Chris Kump-Mitchell, P.E.
Missouri Department of Natural Resources (MDNR)
Hazardous Waste Program
1738 East Elm Street (lower level)
Jefferson City, Missouri 65102

RE: Modine Manufacturing Facility Human Health Risk Assessment
RCRA Facility Investigation Report (RFI), dated July, 2009.
RCRA ID #MOD062439351

Dear Ms. Kump-Mitchell.

The Environmental Protection Agency (EPA) Region 7 has reviewed the human health risk assessment portion of the Modine Manufacturing's RFI Report, dated July 2009.

Based on EPA's review of the risk assessment, EPA does not recommend its approval, stemming mainly from Modine's continued misuse of the trichloroethylene's (TCE) toxicity values. Despite having information to the contrary, Modine has inappropriately used toxicity values provided in TCE's 2001 draft health risk assessment and has disregarded EPA's and MDNR's guidance regarding the use of two tier III toxicity values. The latter is especially problematic in that the "omitted" toxicity values would point to significant weaknesses in the non-cancer inhalation toxicity value used in the risk assessment. The result is a hazard index above one for the indoor worker. Modine must revise the HHRA to include the use of the two tier III toxicity values. EPA is providing the following comments on the risk assessment.

General Comments:

It is evident that Modine's RFI transmittal letter mischaracterizes the guidance EPA provided to them during the April 3, 2009 teleconference and EPA's April 9, 2009 memo regarding TCE toxicity values. The RFI transmittal letter inaccurately suggests that the teleconference discussion was limited to EPA's January 2009 memo on TCE toxicity values. While EPA directed Modine to use New York State Department of Health's (NYSDOH's) non-cancer air criterion during the teleconference, EPA's soon-to-be published April 9, 2009 memo and the status of EPA's 2009 draft *TCE Toxicological Review* including information on the draft toxicity values with emphasis on the draft reference concentration (RfC) were also addressed. In fact, the teleconference call in large part was held because EPA had received advanced notice of the April 9, 2009 memo and a copy of the 2009 draft toxicological review that was undergoing internal Integrated Risk Information System (IRIS) consensus review. EPA's intent was to recommend continued use of the NYSDOH non-cancer air criterion despite the impending developments.

In regards to the April 9, 2009 memo, it withdrew EPA's previous guidance provided in the January 15, 2009 memo on TCE toxicity values so that it could further evaluate the recommendations on the non-cancer toxicity values. It did not specifically withdraw the NYSDOH non-cancer air criterion as a tier III toxicity value or any other toxicity value recommended in the January memo. Modine should be reminded that in addition to the NYSDOH non-cancer air criterion, the withdrawn memo also recommended CalEPA's cancer slope factors and chronic reference exposure level (REL). Furthermore, the April 9, 2009 memo recommended that the regions select TCE toxicity values consistent with EPA's 2003 toxicity value hierarchy (USEPA, 2003). It is EPA's position that the guidance (i.e., use of the NYSDOH non-cancer air criterion) given during the April 3, 2009 teleconference represents the best available science and is consistent with EPA's policy regarding toxicity values in risk assessment.

Specific Comments:

1 The revised risk assessment, dated July 2009, does not account for the *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)* (RAGS Part F) (USEPA, 2009a), which was released in January of 2009. Modine must use RAGS Part F to evaluate the inhalation exposure pathways.

2. Table 5.2 states that a subchronic toxicity value for TCE is not available, which is an erroneous statement. Modine has been made aware of the Agency for Toxic Substances and Disease Registry (ATSDR) intermediate inhalation minimal risk level (MRL) of 537 micrograms per cubic meter ($\mu g/m^3$) in previous comments provided by EPA/MDNR. As a reminder, ATSDR is a source of tier III toxicity values and is listed as such in the risk assessment. ATSDR's intermediate inhalation MRL for TCE **must** be used in the risk assessment to evaluate the non-cancer health hazard for the subchronic construction worker scenario. The use of CalEPA's chronic REL, which is greater than the intermediate MRL, is not appropriate.

   Please note that the omission of ATSDR's intermediate inhalation MRL from the risk assessment is unacceptable and undermines the consistent selection and use of toxicity values. Its omission draws attention away from the fact that it is less (i.e., more health protective) than the chronic REL, which would call into question the health protectiveness of CalEPA's chronic REL when evaluating chronic exposures. Modine is reminded that the discrepancies (i.e., uncertainties) between the toxicity values must be discussed in the uncertainties section and should not serve as the basis for their complete omission from the risk assessment.

3. The use of the toxicity values provided in EPA's draft 2001 TCE health risk assessment is inappropriate and is no longer supported by EPA. The toxicity values in the 2001 draft assessment do not fall within EPA's toxicity value hierarchy nor are they recommended by the Agency. Furthermore, as Modine was made aware during the April 3, 2009 conference call, TCE is being re-evaluated under the IRIS program, and the 2009 draft *TCE Toxicological Review* is currently undergoing peer review. There are significant differences between the toxicity values in the 2009 draft *TCE Toxicological Review* and the 2001 draft assessment. For these reasons, Modine must remove the 2001 draft assessment toxicity values from the risk assessment. This includes the discussion on those values in the text, including the uncertainties discussion, which are no longer relevant.

4. Despite EPA's previous comments and the teleconference, the risk assessment does not utilize the NYSDOH's TCE air criterion of 10 $\mu g/m^3$. Consistent with EPA guidance and policy (USEPA, 2003, 2009c), Modine must use NYSDOH's non-cancer air criterion value for evaluating chronic non-cancer health hazards for the inhalation pathway. The NYSDOH non-cancer air criterion has undergone peer-review and is publicly available. As a result, it is considered a tier III toxicity value. Also, as Modine is aware per the previous teleconference, the NYSDOH air criterion is similar in value to EPA's 2009 draft RfC of 5 $\mu g/m^3$. EPA advises Modine to review the EPA's 2009 draft *TCE Toxicological Review*, which was recently released to the public.

   In addition, Region 7 does not support the use of the CalEPA non-cancer REL, which is 60-fold greater than NYSDOH's non-cancer air criterion. It is EPA's professional judgment that CalEPA's REL does not afford an adequate level of protection for long-term exposures to TCE and therefore, it should not be used in human health risk assessments. EPA's reasons for supporting the use of the NYSDOH's non-cancer air criterion over the CalEPA REL include, but are not limited to, the following:

   The NYSDOH value is based on a more extensive presentation of health endpoints.

   The NYSDOH value is based on a more recent evaluation of the available health effects literature, such as developmental and reproductive effects.

   The NYSDOH's critical study has clear strengths over CalEPA's REL critical study. First, the Rasmussen et al. (1993) study, which was used to derive NYSDOH's air criterion, had 99 subjects compared to CalEPA's critical study, the Vandervort and Polankoff (1973) study, which included 19 subjects. Second, the Rasmussen study evaluated clinical neurological endpoints whereas the Vandervort and Polankoff study looked at self-reported health endpoints via a questionnaire. Also, the Rasmussen study included concurrent biological monitoring that was used to estimate TCE air concentrations via pharmacokinetic modeling. The Vandervort and Polankoff study derived an exposure concentration from one day measurements.

   - The lowest-observed-adverse-effect-level (LOAEL) used to derive the NYSDOH air criterion is 1/6th the LOAEL used to derive the CalEPA REL.

   CalEPA's chronic REL is greater than the ATSDR's intermediate inhalation MRL, which covers exposures lasting from 14 days to 1 year. Although the ATSDR MRL is based on the subchronic rat study by Arito *et al.* (1994), the human pharmacokinetic adjusted LOAEL is similar to that of the human equivalent LOAELs observed in several human studies including the studies used by CalEPA and NYSDOH to derive chronic non-cancer inhalation values (NRC, 2006).

Please note that if Modine continues to use the CalEPA REL (in addition to the NYSDOH non-cancer air criterion), a discussion on the uncertainties associated with the REL must be provided in the risk assessment. The existing uncertainties discussion fails to address any of the uncertainties pertaining to CalEPA's REL, which are clearly evident especially in light of the 2009 draft [TCE Toxicological Review.] Also, Modine agreed to address this comment in their response to MDNR/EPA comments on the April 2008 RFI.

5. The second paragraph of Section 6.6 (p. 6-10) states that the CalEPA toxicity values are based exclusively on mouse inhalation studies. That statement is inaccurate. As noted above, the CalEPA chronic REL is based on a human study. As mentioned in Comment 4, Modine has also failed to address the uncertainties with the CalEPA toxicity values. Additionally, the second paragraph states, "The 'uptake and distribution factors' were reported to be in 'good agreement' with human volunteers." A citation should be provided for this statement because it appears to be summarizing the professional opinion of a person other than the author of the risk assessment.

6. The third paragraph of Section 6.6 (p. 6-11) states that considerable uncertainty exists with EPA's 2001 toxicity values and provides a discussion that is not exclusive to the 2001 draft assessment. Notwithstanding the relevance of the 2001 draft values, the uncertainties and complexities regarding TCE's mechanisms of adverse health effects and carcinogenesis, metabolism, and dose metrics, apply to TCE in general. They too would certainly apply to any toxicity values derived prior to EPA's 2001 draft assessment including CalEPA's toxicity values (i.e., chronic REL and cancer slope factors). Furthermore, the discussion lacks clarity and does not specifically address any of the inhalation toxicity values. The only toxicity value mentioned in the paragraph is the draft oral reference dose. Per Comment 3 and the simple fact that this paragraph does not discuss the uncertainties regarding the 2001 draft toxicity values, the entire paragraph must be removed.

7. In the second to last paragraph of Section 6.6 (p. 6-11), Modine states that the estimation of risks using CalEPA's toxicity values is expected to be "more representative of the inhalation pathway" compared to USEPA's draft 2001 values, which are based on more current science. This statement lacks sound scientific support (per Comments 4, 5 & 6) and is irrelevant, especially with regard to the non-cancer toxicity values and in light of EPA's 2009 draft TCE toxicological review. Modine must remove the discussion pertaining to the draft 2001 values. The discussion should be replaced with a discussion on the uncertainties with the CalEPA and NYSDOH toxicity values with consideration given to EPA's 2009 draft *TCE Toxicological Review.*

If you have any questions regarding these comments, you may reach me at (913) 551-7159 or at Garrett.David@epa.gov.

Sincerely,

David Garrett

David Garrett
Environmental Scientist
RCRA Corrective Action & Permits Branch
Air and Waste Management Division

bcc: Jeremy Johnson, EPA
Lynn Slugantz, EPA

References

Arito, H., M. Takahashi, H. Tsuruta, and T. Ishikawa. 1994. Age-related changes in electrocardiographic responses to trichloroethylene inhalation in conscious rats. Ind. Health 32(3):129-144.

NRC. 2006. Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues. National Academies Press. Washington, DC.

NYSDOH. 2006. Trichloroethene Air Criteria Document. Center for Environmental Health, Bureau of Toxic Substance Assessment, Troy, NY. Available on-line at http://www.health.state.ny.us/environmental/chemicals/trichloroethene/docs/cd_tce.pdf.

Rasmussen K., P. Arlien-Soborg, and S. Sabroe. 1993. Clinical neurological findings among metal degreasers exposed to chlorinated solvents. Acta. Neurol. Scand. 87:200-204.

U.S. EPA. 2003. Human Health Toxicity Values in Superfund Risk Assessments. Office of Solid Waste and Emergency Response, Washington D.C. OSWER Directive 9285.7-53.

U.S. EPA. 2009a. Regional Screening Table. Available on-line at http://www.epa.gov/reg3hwmd/risk/human/index.htm

U.S. EPA. 2009b. *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment).* Office of Emergency and Remedial Response, Washington, D.C. EPA-540-R-070-002.

U.S. EPA. 2009c. Withdrawal of the January 15, 2009, OSWER Guidance Entitled: "Interim Recommended Trichloroethylene (TCE) Toxicity Values to Assess Human Health Risk and Recommendations for Vapor Intrusion Pathway Analysis. Memo from Barry Breen, Acting Assistant Administrator, OSWER, to Acting Regional Administrators. April 9, 2009.

Vandervort, R. and P. Polakoff. 1973. Health Hazard Evaluation Report HHE-72-84-31 Dunham-Bush, Inc., West Hartford, Connecticut. Hazard Evaluation Services Branch, National Institute for Occupational Safety and Health, Cincinnati, OH.